Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims

Please substitute the following listing of claims for the previous listing of claims:

1. (Currently amended) A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising particles comprising a hollow and porous lipid matrix and an active agent, ~~and~~ the particles having a particle size of ~~1-30~~ 0.5 to 20 microns, mass median aerodynamic diameter of less than about 5 microns, and the powder comprising a bulk density of less than 0.5 g/cm^3;

loading the dry powder composition into a passive dry powder inhaler having ~~a resistance of from 0.01 to 0.30 $(cmH_20)^{1/2}/Lmin^{-1}$~~ an inhalation flow rate range of about 10 to about 60 L/min; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein the emitted dose is at least 60% and a lung deposition is at least 25% over substantially the flow rate range of the inhaler ~~the lung deposition is greater than 25% for flow rates from 10 to 60 liters per minute~~.

2-4. (Cancelled)

5. (Previously presented) A method according to claim 1 wherein the lipid comprises a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidycholine, dibehenoylphosphatidylcholine,

diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols.

6-12. (Cancelled)

13. (Original) A method according to claim 1 wherein the lung deposition is greater than 50%.

14. (Currently amended) A method according to claim 1 wherein the active agent is selected from the group consisting of budesonide, tobramycin sulfate, leuprolide acetate, amphotericin B, ciprofloxacin, and parathyroid hormone.

15-28. (Cancelled)

29. (Currently amended) A method for the pulmonary administration of a dry powder composition from a passive dry powder inhaler to the respiratory tract of a patient, the method comprising:

providing a dry powder composition comprising hollow and porous particles comprising:

(i) a ~~lipid~~ phospholipid matrix comprising a phospholipid selected from the group consisting of dipalmitoylphosphatidylcholine, distearoylphosphatidylcholine, diarachidoylphosphatidycholine, dibehenoylphosphatidylcholine, diphosphatidyl glycerol, phosphatidylcholines, saturated phosphatidylethanolamines, saturated phosphatidylserines, saturated phosphatidylglycerols, and saturated phosphatidylinositols;

(ii) an active agent comprising tobramycin ~~sulfate~~;

(iii) a particle size of ~~1-30~~ 0.5 to 20 microns; and

(iv) a mass median aerodynamic diameter of less than 5 microns; ~~and~~

~~(v) a bulk density of less than 0.5 g/cm^3;~~

loading the dry powder composition into a passive dry powder inhaler having a range of inhalation flow rates ~~resistance of from 0.01 to 0.30 (cmH$_2$0)$^{1/2}$/Lmin^{-1}~~; and

administering the dry powder composition from the inhaler to the respiratory tract of a patient,

wherein ~~the~~ a FPF_{4+F} fine particle fraction ~~(FPF_{4+F})~~ emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger, an emitted dose is at least about 60%, and is substantially independent of an inhalation flow rate, and wherein a lung deposition is greater than 25%, an interpatient variation in lung deposition is less than about 17%, and an intrapatient variation in lung deposition is less than about 6%.

30-34. (Cancelled)

Add new claims 35-47 as follows:

35. (New) The method of claim 1 wherein a FPF_{4+F} fine particle fraction emitted from the inhaler is at least 60% as determined by an Anderson Cascade Impaction or multi-stage liquid impinger.

36. (New) The method of claim 1 wherein the particles further comprise a metal cation.

37. (New) The method of claim 1 wherein the metal cation comprises calcium.

38. (New) The method of claim 1 wherein a difference between lung deposition at about 30 LPM and lung deposition at about 90 LPM is about 11% or less, as measured by FPF_{4+F}.

39. (New) The method of claim 1 wherein the active agent comprises tobramycin, and an intrasubject dose variability is about 6% or less.

40. (New) The method of claim 1, where a variation in FPF_{4+F} with inhalation flow rate is less than about 20%.

41. (New) The method of claim 1 wherein an interpatient variation in lung deposition is less than about 17%.

42. (New) A powder for inhalation comprising:

particles comprising an active agent and a phospholipid matrix wherein the particles are characterized by a hollow and/or porous matrix, a size of about 0.5-20 microns, a MMAD of less than 5 microns, and wherein the powder is characterized by a bulk density less than 0.5 g/cm^2; and

the powder, when used with a passive dry powder inhaler device, provides an emitted dose and a lung deposition substantially independent of an inhalation flow rate, and wherein a variation in lung deposition, as measured by a FPF_{4+F}, is less than about 20%.

43. (New) The particles of claim 42 further comprising a metal cation.

44. (New) The particles of claim 43 further wherein the metal cation comprises calcium.

45. (New) The powder of claim 42 wherein the active agent comprises tobramycin, and a difference between lung deposition at about 30 LPM and lung deposition at about 90 LPM is about 11% or less, as measured by FPF_{4+F}.

46. (New) A kit comprising:

a passive dry powder inhaler, having a resistance of from 0.01 to 0.30 $(cmH_20)^{1/2}/Lmin^{-1}$ and permitting an inhalation flow rate range of about 10 to about 90 L/min; and

a powder for inhalation, the powder comprising particles comprising an active agent and a phospholipid matrix wherein the particles are characterized by a hollow and/or porous matrix, a size range of about 0.5 to 20 microns, a MMAD of less than about 5 microns, and wherein the powder is characterized by a bulk density less than about 0.5 g/cm^2; and wherein an emitted dose is at least about 60%, and is substantially independent of an inhalation flow rate, and

wherein an interpatient variation in lung deposition is less than about 17%, and wherein an intrapatient variation in lung deposition is less than about 6%.

47. (New) A method for inhalation of a dry powder drug with reduced variability in the lung dose comprising:

providing a dry powder drug composition comprising particles comprising a lipid matrix and a particle size of 1-30 microns, mass median aerodynamic diameter of less than 5 microns, and a bulk density of less than 0.5 g/cm^3;

loading the composition into a passive dry powder inhaler; and

inhaling the drug composition from the inhaler resulting in lung deposition wherein a variability between patients at a single flow rate is less than about 17%, and a variability with flow rate is less than about 20%.